DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 18, 2014

Edwards Lifesciences
% Neil Delaney
Regulatory Affairs Project Manager
One Edwards Way
Irvine, California 92614

Re: K141696
Trade/Device Name: Edwards eSheath Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 23, 2014
Received: June 24, 2014

Dear Neil Delaney,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141696

Device Name
Edwards eSheath Introducer Set

Indications for Use *(Describe)*
The Edwards eSheath Introducer Set is indicated for the introduction of the Edwards SAPIEN XT Transcatheter Heart Valve and associated devices into the vascular system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) Summary

Submitter: Edwards Lifesciences, LLC
One Edwards Way
Irvine, CA 92663

Contact: Neil Delaney Phone: 949-250-2500, Fax: 949-756-4408

Prepared: June 6, 2014

Trade Name: Edwards eSheath Introducer Set

Common Name: Catheter, Introducer

Classification: Catheter Introducer
21 CFR 870.1340, Product Code DYB

Predicate Devices: RetroFlex 3 Introducer Sheath Set (K093877)
Solopath Balloon Expandable Transfemoral Introducer (K100819)

Device Description:
The Edwards eSheath Introducer Set consists of a sheath, introducer, and loader. It is provided sterile for single use and is compatible with a standard 0.035" guidewire.

The sheath shaft is comprised of a PTFE inner liner and a HDPE/TecoFlex coextruded outer layer with a folded seam that can temporarily expand if a device is passed through that is larger than the sheath's inner diameter, and a TecoFlex outer cover that encapsulates the seam. The exterior includes a hydrophilic coating to facilitate introduction into the target vessel. The distal end of the shaft features a platinum/iridium radiopaque marker for visibility, and the sheath shaft mates proximally with a housing that contains an extension tube used for flushing of the sheath and three valves (seals) to provide hemostasis.

The introducer is made from polyethylene with barium sulfate for radiopacity, and features a hydrophilic coating to facilitate entry and trackability of the sheath into the vessel. The introducer is tapered with an atraumatic distal tip and a lumen to accommodate a 0.035" guidewire.

The loader may be used to aid in the insertion of devices into the sheath and may be removed so that the entire working length of the inserted device can be utilized. The loader housing contains a valve (seal) to provide hemostasis.

Intended Use:
Entry of interventional devices into the vascular system

Indication:
Indicated for the introduction of the Edwards SAPIEN XT Transcatheter Heart Valve and associated devices into the vascular system.

Comparison to Predicate:
The Edwards eSheath Introducer Set is substantially equivalent in function, performance, and design to the RetroFlex 3 Introducer Sheath Set (K093877) and Solopath Balloon Expandable Transfemoral Introducer (K100819). The Edwards eSheath and the Solopath Introducer have an expandable shaft.

The Edwards eSheath is expanded in the vasculature by the device that is passed through the inner diameter and the Solopath Introducer is expanded in the vasculature via inflation. The eSheath device compatibility testing was completed using the Edwards SAPIEN XT Transcatheter Heart Valve and NovaFlex+ delivery system. The RetroFlex 3 Introducer Sheath Set has the same proximal end (housing, hemostasis control, and flush tube) and introducer as the Edwards eSheath but does not include the expansion feature. Additional differences from the predicates are material changes to the sheath shaft and to the sheath radiopaque marker, and the addition of a perforation feature to the loader shaft so that it can be peeled away and removed.

Summary of Non-Clinical Testing:
Non-clinical testing was completed to demonstrate that the performance characteristics of the Edwards eSheath Introducer Set are equivalent to the predicates, and to verify that design requirements are satisfied. Specifically, the following design verification and validation testing was successfully completed:

- Visual Surface Inspection
- Dimensional Inspection
- Radiopacity/Visualization
- Guidewire Compatibility
- Hemostasis
- Kink Resistance
- Seam Return After Expansion
- Bond Strength
- Loader Peel Test
- Device Interaction
- Hydrophilic Coating Integrity
- USP Particulate Test
- Sterilization Validation
- Biocompatibility Tests:
  - Cytotoxicity
  - Hemocompatibility
  - Systemic Toxicity
  - Material Mediated Pyrogenicity
  - Irritation/Intracutaneous Reactivity
  - Sensitization
  - Chemical Acceptability
- Thrombogenicity
- Packaging Integrity
- Shelf Life Verification

Conclusion:
Based upon device testing and descriptive characteristics, the Edwards eSheath Introducer Set is substantially equivalent to the predicate device and performance testing has demonstrated that safety and efficacy are not adversely impacted.